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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/982,093 | 10/19/2001 | S. Rao Chenukuri | 24222-X3 | 6757 |

7590 07/14/2004

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EXAMINER

FUBARA, BLESSING M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1615

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/982,093 | CHERUKURI, S. RAO | |
| | Examiner | Art Unit | |
| | Blessing M. Fubara | 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 8-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, declaration under 37 CFR 1.132, amendment and remarks all filed 04/15/04. Claims 1-24 are pending.

Claim Rejections - 35 USC § 103

1. Claims 1-7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jerussi et al (US 6,197,828) in view of Amey et al. (US 6,245,350).

Applicant states that the references of record do not teach or suggest the claimed invention; there is no teaching or suggestion in the references that would lead one of ordinary skill in the art to modify the references to arrive at the subject of the amended claims with any expectation of success at the time the invention was made. Applicant argues that the prior art does not teach a caplet that has a diameter and length from about 1 millimeter to about 7 millimeter and that Amey fails to cure the deficiency of Jerussi because the combined references failed to teach the small size of the caplets as required by the instant claims. Applicant submitted a declaration under 37 CFR 1.132 in which applicant opined the following:

- a) “The small size is critical for accurate, reproducible, multiple plural releases of delivery of the pharmaceutical when administered to a mammal. That the same formulation incorporated into larger product results in different dose delivery of the pharmaceutical;” and “the smaller caplet size increases the surface area of the delivery system” that leads to “better and more accurate delivery of the pharmaceutical to the mammal.”
- b) “That the smaller size of the product provides faster dissolving of the caplets and thereby faster delivery of the pharmaceutical to the mammal.”

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c) "That better accurate reproducible controlled dosing of pharmaceuticals has been desired in the health care industry, and the present inventive product provides better control via smaller size of the dosing unit."

Applicant thus opined and concluded that one of ordinary skill in the art would not be lead to modify or improve either of the cited patents in an attempt to achieve the claimed invention based on the differences in the types of extracts as discussed.

Response to Arguments

2. Applicant's arguments filed 04/15/04 have been fully considered but they are not persuasive.

Applicant's argument is directed to differences in the size of the caplet and differences in size would not support the patentability of applicant's caplet over the caplet of the prior art. No modification of the size of the pellet is necessary in this case. Applicant has no comparable data to show that the caplet of prior art in terms of the size does not meet all the arguments presented above or the size of applicant's caplet in relation to any known caplet does not have those attributes listed above. Amey is relied upon for a teaching of encapsulating caplets.

Response to the 1.132 declarations:

The declaration is applicants opinion and the opinion is not supported by data. Applicant provided no experimental data to support the opinion. A showing/experimental data supporting applicants opinion is necessary to demonstrate that the caplet of the prior art does not posses the attributes declared in the opinion in the 1.132 declarations. In the absence of a showing, caplet having the recited size is not patentable over the caplet of the prior art. Applicant provided no comparable data to show that the caplet of the prior art in terms of the size does not meet all the

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arguments presented above or the size of the applicants caplet in relation to any known caplet does not have those attributes listed above.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

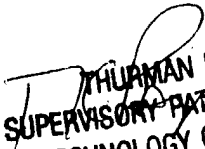
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 Blessing Fubara
Patent Examiner
Tech. Center 1600


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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